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Research Article

A Randomized Controlled Clinical Study to Evaluate Add-on Effect of *Baladi* Granules in the Management of *Karshya Vyadhi* (Mild to Moderate Undernutrition) in Children

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Abstract

Background: Protein-energy malnutrition is a major contributor to childhood morbidity and mortality in India, with one-third of children under five undernourished. Ayurveda describes *Karshya Vyadhi* as undernutrition, managed with *Brimhana* and *Balya* therapies. Baladi Granules, a polyherbal, child-friendly formulation (*Sida cordifolia*, *Withania somnifera*, *Asparagus racemosus*, *Glycyrrhiza glabra*, *Saccharum officinarum*, with *Zingiber officinale* and *Elettaria cardamomum*), were developed to improve appetite, digestion, and growth. Materials and Methods: A randomized, controlled, open-label clinical trial was conducted on 122 children (1–12 years) with mild-to-moderate undernutrition (weight-for-age 60–80%, IAP classification) at Dr. D. Y. Patil Ayurved Hospital, Pimpri, Pune. Participants were randomized into Group A (*Baladi* Granules + standard undernutrition diet) and Group B (diet alone). Intervention lasted 30 days. Primary outcome was change in weight-for-age and body weight; secondary outcomes included MUAC, height-for-age, muscle wasting, hunger, general appearance, weakness, adherence, and safety. Results: Out of 122 enrolled, 116 completed the trial. Group A demonstrated significantly greater mean weight gain (0.48 kg vs. 0.26 kg), MUAC improvement (0.43 cm vs. 0.30 cm), and more linear growth (0.64 cm vs. 0.41 cm) compared to controls. Subjective parameters (hunger, general appearance, weakness, muscle wasting) also improved more in Group A, with 53.45% showing marked improvement versus 20.69% in controls. No adverse events were reported. Conclusions: *Baladi* Granules, as an adjunct to diet, are safe, palatable, and effective in improving anthropometric and clinical outcomes in children with undernutrition. Further large-scale studies are warranted.

Keywords: *Karshya Vyadhi*, *Baladi* Granules, Undernutrition, *Ayurveda*, Children, Randomized controlled trial

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Introduction

Protein energy malnutrition remains one of the leading contributors to morbidity and mortality among children in India. Undernutrition accounts for nearly 45% of global mortality among children below five years of age(1).The National Family Health Survey (NFHS-4) reports that 36% of children under five in India are underweight, with the burden being greater in rural than in urban areas.In Pune, undernutrition affects 27.9% of the rural pediatric population compared to 23.6% in urban areas(2). The prevalence is similar in boys and girls. Undernutrition during early childhood can result in irreversible physical, cognitive, and developmental impairments.

Ayurveda describes *Karshya Vyadhi* as a state of undernutrition, and several classical formulations including *Preenan Modak*(3), *Balpanchamruta Churna*(4), *Pathadi Churna*(5), and *Vachadi Ghrita*(6) have demonstrated benefits in improving body weight and nutritional status in children. Many existing studies are constrained by factors such as limited sample sizes, brief

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treatment durations, and reliance on single-arm methodologies. Additionally, traditional Ayurvedic dosage forms like *Churna* and *Ghrita*, though efficacious, are often unpalatable and inconvenient for pediatric administration.

There remains a lack of large-scale randomized controlled trials evaluating child-friendly, palatable Ayurvedic dosage forms. *Baladi* Granules have been formulated to address this gap, containing *Bala (Sida cordifolia), Shatavari (Asparagus racemosus), Ashwagandha (Withania somnifera),Yashtimadhu (Glycyrrhiza glabra), Khand (Saccharum officinarum), Shunthi (Zingiber officinale), and Ela (Elettaria cardamomum)*. These ingredients are cost-effective, widely available, and safe for pediatric use.

Since children with undernutrition require dietary support beyond a normal diet and protein supplements may be unsuitable for children under three years due to renal immaturity(7). For children aged 1–12 years with mild to moderate undernutrition (*Karshya Vyadhi*), *Baladi* Granules serve as a holistic, safe, and child-friendly therapeutic alternative.

Materials and methods

Research design

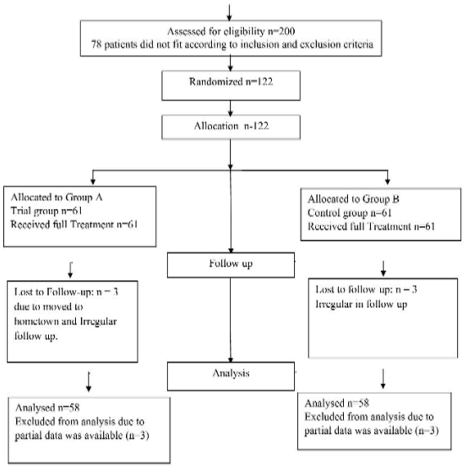
The Kaumarbhritya Department of the Dr. D. Y. Patil Ayurved Hospital and Research Centre Pimpri, Pune, was the site of this prospective, open-label, randomized, controlled clinical study.The trial lasted 36 months in total.

Participants

A total of 122 children (aged 1–12 years) with mild-to-moderate undernutrition (weight-for-age 60–80%, IAP classification) were enrolled after obtaining parental informed consent(8).Children with severe undernutrition, chronic or infective diseases, immunodeficiency, inborn errors of metabolism, malignancies, or genetic disorders were excluded.

Participants were randomized (block randomization; chit-in-envelope) into two equal groups: Group A (Trial, n = 61): *Baladi* Granules (1 g/year of age, twice daily with 100 mL milk before meals at 08:00 and 18:00) plus standard undernutrition diet (IAP guidelines) (9). Group B (Control, n = 61): Standard undernutrition diet alone(10). Intervention lasted 30 days with follow-ups on Days 15 and 30. Adherence was assessed via caregiver charts and unused drug counts. Withdrawal criteria were refusal, migration, or adverse effects.

Fig.1.CONSORT Flow Diagram of Patient Enrollment



Drug Preparation Method

Baladi Granules were prepared following standard Ayurvedic procedures. Cleaned crude drugs were processed into decoction, filtered, and mixed with sugar. The mixture was stirred to semi-solid consistency, converted into granules, sieved, dried, and stored in airtight containers. (see supplementary files for more details)

Institutional Ethics Committee Ref. No: DYPCARC/IEC/99/2023

CTR Registration Number: CTRI/2024/03/063618

Primary Outcome

Criteria for Assessment

Primary Outcome:

- **Weight-for-Age (IAP Classification):** Improvement in nutritional status based on weight-for-age percentage.
- **Primary endpoint:** Mean change in body weight (kg) from baseline to Day 30.

Secondary Outcomes:

- **Anthropometric:** MUAC (Arnold's classification) (11), Height-for-Age(12).
- **Subjective:** State of Hunger (*Kshudha*) (13), General Appearance (*Darshana*) (13), and General Weakness (*Daurbalya*) (14), clinical assessment of muscle wasting (*Shushkasphik-Udar-Griva*) (15).
- **Other:** Treatment adherence (drug accountability/caregiver charts) and safety outcomes (adverse drug reactions).

Assessment Schedule

All parameters were assessed at baseline, Day 15, and Day 30 using predefined grading scales. Cumulative scores were compared to evaluate clinical improvement.

Statistical Analysis

A total of 122 children were recruited, with 61 allocated to each group. Three participants from both the trial and control groups discontinued, resulting in 58 subjects per group included in the final evaluation. Demographic data were expressed as frequencies and percentages and represented graphically. Ordinal variables were examined using the Wilcoxon signed-rank test for intra-group comparisons and the Mann–Whitney U test for inter-group analyses. Continuous data were evaluated using paired and unpaired t-tests, as the population standard deviation was not known. A p-value < 0.05 was deemed statistically significant, and all analyses were performed using SPSS software version 20.0 (IBM Corp., Armonk, NY, USA).

Observations and Results

A total of 122 children were enrolled, with 61 in each group. The average age of participants was 4.35 ± 2.56 years in Group A and 5.20 ± 3.08 years in Group B.Gender distribution was nearly equal, with 31 males and 30 females in each group.The majority of participants were Hindu, accounting for 88.5% in Group A and 96.7% in Group B, from middle socioeconomic class (70.5% and 67.2% respectively), and followed a mixed diet (63.9% and 80.3%). *Prakruti* analysis showed VP type as predominant in both groups. Baseline characteristics including age, sex, religion, socioeconomic status, diet, and *prakruti* were comparable between groups, confirming successful randomization.

Table 1: Patient Profile

Sr. No.	Clinical Profile		Group A (Trial)	Group B (Control)
1	Age (Years)		4.35 ± 2.56	5.20 ± 3.08
2	Sex	Male	31 (50.82%)	31 (50.82%)
		Female	30 (49.18%)	30 (49.18%)
3	Religion	Buddhist	1 (1.64%)	0 (0.00%)
		Hindu	54 (88.52%)	59 (96.72%)
		Jain	1 (1.64)	0 (0.00%)
		Muslim	5 (8.20)	2 (3.28%)
4	Socio Economic Status	Lower	7 (11.48%)	13 (21.13%)
		Middle	43 (70.49%)	41 (67.21%)
		Higher	11 (18.03%)	7 (11.48%)
5	Diet	Mixed	39 (63.93%)	49 (80.33%)
		Veg	22 (36.07%)	12 (19.67%)
6	*Prakruti*	KP	15 (24.59%)	18 (29.51%)
		KV	4 (6.56%)	1 (1.64%)
		PK	4 (6.56%)	2 (3.28%)
		PV	3 (4.92%)	4 (6.56%)
		VK	1 (1.64%)	4 (6.56%)
		VP	34 (55.74%)	32 (52.46%)

Objective Parameters

Table 2: Objective parameters

Sr. No	Clinical Variables	Groups	1st Day	15th Day	30th Day	P-Value
1	Weight for Age	A (Trial)	13.74 ± 4.58	14.00 ± 4.60	14.22 ± 4.59	<0.001
		B (Control)	15.56 ± 5.67	15.68 ± 5.68	15.82 ±5.67	<0.001
2	MUAC	A (Trial)	15.38 ± 1.43	15.44 ± 1.44	15.80 ± 1.43	<0.001
		B (Control)	15.86 ± 1.62	15.89 ± 1.65	16.16 ± 1.72	<0.001
3	Height for Age	A (Trial)	98.17 ± 17.52	98.49 ± 17.48	98.81 ± 17.43	<0.001
		B (Control)	104.84 ± 21.10	104.97 ± 21.10	105.25 ± 21.10	<0.001

Clinical Assessment Outcomes (Objective parameters)

Both groups showed significant improvements in anthropometric indicators ($p < 0.001$). In the Trial group, Weight for Age increased by 3.48% compared to 1.64% in the Control group, while MUAC improved by 2.77% versus 1.90% in controls. Height for Age showed minimal change in both groups (<1%). Overall, the Trial group demonstrated earlier and greater gains, particularly in Weight for Age and MUAC, indicating a more pronounced effect of *Baladi* Granules on nutritional status.

Subjective Parameters

Table 3: Subjective parameters

Sr. No	Clinical Variables	Groups	1st Day	15th Day	30th Day	P-Value
1	State of Hunger	A (Trial)	1.60 ± 0.59	0.67 ± 1.55	0.00 ± 0.00	<0.001
		B (Control)	1.67 ± 0.47	1.55 ± 0.50	0.71 ± 0.59	<0.001
2	General appearance	A (Trial)	1.33 ± 0.54	1.29 ± 0.53	0.71 ± 0.59	<0.001
		B (Control)	1.19 ± 0.40	1.17 ± 0.42	0.88 ± 0.50	<0.001
3	General Weakness	A (Trial)	1.16 ± 0.37	0.34 ± 0.55	0.05 ± 0.22	<0.001
		B (Control)	1.19 ± 0.40	1.10 ± 0.36	0.26 ± 0.55	<0.001
4	Wasting of muscles	A (Trial)	1.31 ± 0.47	1.26 ±0.44	0.45 ± 0.54	<0.001
		B (Control)	1.19 ± 0.40	1.19 ± 0.40	0.59 ± 0.62	<0.001

Clinical Assessment Outcomes (Subjective Parameters)

Both groups showed significant improvements ($p < 0.001$) in hunger, general appearance, weakness, and muscle wasting. In the Trial group, State of Hunger improved completely by day 30 (100% vs. 57.7% in controls). General Appearance improved by 46.8% compared to 26.1% in the Control group. General Weakness showed 95.5% improvement versus 78.3% in controls. Muscle Wasting reduced by 65.8% compared to 50.7% in controls.Overall, the Trial group demonstrated earlier, faster, and greater improvements across all subjective parameters, confirming the superior efficacy of *Baladi* Granules as an add-on therapy.

Table 4: Overall improvement in Group A (Trial) and Group B (Control) according to number of patients.

Overall Effect	Group A (Trial)		Group B (Control)	
	N	%	N	%
Marked Improvement	31	53.45%	12	20.69%
Moderate Improvement	24	41.38%	22	37.93%
Mild Improvement	3	5.17%	15	25.86%
No Improvement	0	0.00%	9	15.52%
TOTAL	58	100.00%	58	100.00%

In Group A, 53.45% of patients showed marked improvement (>75%), 41.38% demonstrated moderate improvement (51–75%), and 5.17% exhibited mild improvement (26–50%). In contrast, Group B showed marked improvement in 20.69%, moderate improvement in 37.93%, mild improvement in 25.86%, and no improvement in 15.52% of patients.

Discussion

According to Ayurveda Karshya is defined as a lean and thin body constitution (*Krisha Sharira*), primarily resulting from *Dhatukshaya*, with a special emphasis on *Mamsakshaya(16)*. Charaka Samhita describes symptoms like poor tolerance to exertion, hunger, thirst, and climate extremes.Clinically, it presents with emaciation, sunken buttocks, abdomen, and neck, and visible veins (*Shushka sphik-udara-greeva*) (15).These findings resemble biomedical undernutrition, marked by low weight-for-age and muscle wasting.Thus, Karshya correlates closely with undernutrition, bridging Ayurvedic and modern perspectives.

This randomized controlled trial was conducted to assess the adjunctive efficacy of Baladi Granules in managing mild-to-moderate undernutrition (Karshya Vyadhi) among children.Demographic analysis revealed that most participants were aged 1–5 years, highlighting the higher vulnerability of early childhood to undernutrition. Gender distribution was balanced, indicating no sex-related bias. The majority belonged to the middle socio-economic class and followed a mixed diet, consistent with local population characteristics. Predominant *Vata–Pitta Prakriti* was observed, which aligns with Ayurvedic concepts, as *Vata* dominance predisposes to lean body habitus, variable appetite, and *dhātu kṣaya*.

Objective anthropometric outcomes demonstrated significant improvements in both groups, with superior results in the trial group receiving *Baladi Granules*. Children in Group A showed greater mean weight gain (0.48 kg vs. 0.26 kg), higher MUAC improvement (0.43 cm vs. 0.30 cm), and more linear growth (0.64 cm vs. 0.41 cm) compared to controls.These results suggest that *Baladi Granules* contributed to better weight restoration, muscle development, and growth.

Subjective parameters further supported these findings. Group A demonstrated marked improvements in appetite, general appearance, and vitality compared to controls. Clinical assessments revealed faster recovery in hunger perception (*Kshudha*), better physical outlook (*Darshana*), and reduced weakness (*Daurbalya*).Reduction in muscle wasting was also more pronounced in Group A, reflecting enhanced tissue nourishment. Overall response rates indicated that 53.45% of children in Group A achieved marked improvement, compared to only 20.69% in Group B, while none in the trial group remained unimproved. This highlights the efficacy of the formulation in improving both physical and functional health outcomes.

The therapeutic effects of *Baladi Granules* can be explained through Ayurvedic principles and modern pharmacology.The dose of *Baladi* Granules was based on the age-wise pediatric dosing principles described in Sharangadhara Samhita (Prathama Khanda 6/14–16). Since the formulation was administered in a coarse granule form, it was considered analogous to Churna Kalpana, and the dose was fixed as 1 g per year of age, twice daily.The formulation possesses *Brimhana* (bulk-promoting), *Balya* (strength-promoting), *Rasayana* (rejuvenative), and *Vata-pacifying* properties, which enhance *Agni*, assimilation, and *dhātu poṣhana(17)(18)(19)*. The key ingredients *Sida cordifolia, Withania somnifera, Asparagus racemosus, Glycyrrhiza glabra,* and *Saccharum officinarum* support muscle mass, immunity, digestion, and energy(20)(21)(22).The adjuvants *Zingiber officinale* and *Elettaria cardamomum* act as *Deepana* and *Pachana*, improving appetite and reducing gastrointestinal discomfort(18)(23). Collectively, these actions facilitated faster weight gain, improved MUAC, and better overall growth in undernourished children.

In addition, the standard undernutrition diet, designed according to IAP guidelines and enriched with calorie-dense and protein-rich foods, played a crucial role in recovery across both groups. High-calorie items (ghee, cashews, jaggery), protein sources (soybeans, eggs, chicken), and micronutrient-rich foods (pulses, fish, almonds) promoted weight gain, tissue repair, and immune function(24). Fermented foods and buttermilk improved gut health, while culturally acceptable items ensured dietary adherence. While both groups benefited from diet, the trial group exhibited accelerated and greater improvements due to the synergistic effect of *Baladi Granules.*Both groups maintained a steady post-intervention weight gain of 300–400 g per month, indicating sustained nutritional recovery.Thus, the study concludes that *Baladi Granules* are a safe and effective adjunct to standard dietary therapy in pediatric undernutrition, warranting further large-scale and long-term studies for confirmation.

Conclusion

Baladi Granules, as an adjunct to standard undernutrition diet, significantly improved weight, MUAC, and height in children with mild to moderate undernutrition. The formulation is safe, cost-effective, and showed no adverse effects, highlighting its potential as a supportive therapy in pediatric nutrition.

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Conflicts of Interest: None declared.

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